

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

* * * * *

RYAN L. SWICK and MARY M. SWICK, *

legal representatives and parents of their *
deceased minor child, J.R.S., *

Petitioners, *

v. *

SECRETARY OF HEALTH *
AND HUMAN SERVICES, *

Respondent. *

* * * * *

No. 13-526V
Special Master
Christian J. Moran

Filed: February 26, 2018

Entitlement, infant's death,
posterior reversible
encephalopathy syndrome
(PRES)

Richard H. Moeller, Berenstein, Moore, Heffernan, Moeller & Johnson, L.L.P.,
Sioux City, IA, for petitioners;
Ryan D. Pyles, United States Dep't of Justice, Washington, DC, for respondent.

PUBLISHED DECISION DENYING COMPENSATION¹

The facts in this case are sad. A medical examiner found that the death of J.R.S., who was nearly 3 months old, was "unexplained." Exhibit 6 at 15. J.R.S.'s parents, Ryan L. Swick and Mary M. Swick, claim that vaccinations caused their son to die approximately 17 days following their administration.

Although their story is emotionally compelling, the petitioners' evidence is not legally persuasive. Beyond sympathy, the Swicks' claim that the vaccinations caused J.R.S.'s death depends on the value of an opinion from their expert, Walter E. Kozachuk, a doctor who specializes in neurology. However, his qualifications

¹ The E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002), requires that the Court post this ruling on its website. Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa-12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

and credentials in the relevant disciplines are not as strong as the background of Michael H. Kohrman, a board-certified neurologist whom the Secretary has retained. Besides the disparity in credentials between the experts, the diagnosis that Dr. Kozachuk has proposed is not reliable or persuasive. Dr. Kozachuk has opined that J.R.S. suffered from posterior reversible encephalopathy syndrome (PRES), but the evidence does not support this diagnosis. Because the remainder of Dr. Kozachuk's opinion that the vaccinations caused J.R.S.'s death depends upon the diagnosis of PRES, Dr. Kozachuk's overall opinion on causation is not persuasive. A full discussion follows.

Facts²

The relevant facts in this tragic case can be stated relatively succinctly.³ For a more detailed recitation of information, see Ruling Finding Facts, issued Jan. 7, 2016; Pet'rs' Proposed Findings of Fact, filed Dec. 22, 2014; and Resp't's Resp. to Pet'rs' Proposed Findings of Fact, filed Jan. 20, 2015.

After a gestation of 36 weeks and 3 days, J.R.S. was born on May 14, 2011. Soon after delivery, he had some difficulty breathing and required intubation for less than 24 hours. Exhibit 10 at 2-3. Although he had some additional difficulties with feeding (an immature and disorganized suck), he gained weight shortly after being born.

J.R.S. often experienced constipation that seemed to make him fussy. J.R.S. had a well-child examination on July 25, 2011. Concerns included constipation that glycerin suppositories were helping and crying from 2:00 AM to 7:00 AM daily. Exhibit 2 at 25. During this appointment, J.R.S. received the hepatitis B, rotavirus, diphtheria-tetanus-acellular pertussis, haemophilus influenzae type b, inactivated poliovirus, and pneumococcal conjugate vaccines. Id. at 26.

Between July 25, 2011, and August 11, 2011, J.R.S. continued to have episodes of constipation during which he was fussy. In early August, he vomited a large amount once. Findings of Fact at 14-15.

² As discussed in the procedural history below, some of the facts were found after a hearing during which percipient witnesses testified.

³ In accord with 42 U.S.C. § 300aa-13(a)(1), the undersigned has considered the entire record. However, this decision does not discuss all the evidence.

In the days before J.R.S.'s death on August 11, 2011, his mother, father, and two older siblings were ill with colds. Exhibit 6 at 11 (medical examiner's questionnaire). In the evening of August 10, 2011, J.R.S. began to cough and his coughing woke him from his sleep. Findings of Fact at 15.

The evidence regarding whether J.R.S. was placed on his back (supine) or stomach (prone) was inconsistent and no finding is required. J.R.S. was found in the prone position. A blanket was covering his head. Exhibit 6 at 10; Findings of Fact at 15.

When Mrs. Swick found J.R.S., he was warm to the touch, sweaty, pale, limp, and still. His face and lips were not blue, but the area below J.R.S.'s lips started to turn blue just before Mrs. Swick stopped performing CPR. Findings of Fact at 15.

Mrs. Swick called 911 and emergency medical technicians arrived at their house at approximately 10:00 AM. J.R.S. did not show signs of life. Exhibit 4 at 1, 2, 6; exhibit 5 at 9. The EMTs brought J.R.S. to a local hospital, where he was pronounced dead at 10:39 AM. Exhibit 5 at 10, 11, 21.

Dennis F. Klein, M.D., a deputy state medical examiner, performed an autopsy on August 12, 2011. From the autopsy, Dr. Klein submitted a brain specimen to the University of Iowa for a neuropathologic consultation. Exhibit 6 at 16. The neuropathologist, Patricia A. Kirby, M.D., examined the brain on September 2, 2011, and submitted her report on September 7, 2011. Id. at 28. Dr. Klein sent his report to various people on September 12, 2011. Id. at 14.

In her neuropathology report, Dr. Kirby found "the midbrain, medulla and pons show congestion with focal perivascular hemorrhages in the pons. The basal meninges are congested with smear subarachnoid hemorrhages. The cerebral cortex has persistent but involuting external granular layer." Dr. Kirby continued: "[t]he neocortex shows no acute or remote hypoxic-ischemic neuronal injury and there is no cortical lamination anomaly." She also found "the white matter is within normal limits." Exhibit 6 at 29-30. Dr. Kirby's case summary states "examination of the brain fails to reveal a C[entral] N[ervous] S[ystem] cause of death. Although somewhat non-specific, the findings would be in keeping with an asphyxial death." Id. at 28.

The opinion of the medical examiner, Dr. Klein, was that J.R.S. died of "sudden unexplained infant death." Id. at 20. Dr. Klein added: "Due to the circumstances of how the decedent was found, prone with blanket covering the

head and the non-specific findings in the brain that would be in keeping with asphyxia[,] death caused by asphyxia cannot be ruled out. The manner of death is UNDETERMINED.” Id. at 21.

Procedural History⁴

The Swicks allege a vaccination, or combination of vaccinations, caused J.R.S.’s death. Pet., ¶¶ 21, 23. To support their claim for compensation, petitioners filed medical records (exhibits 1-6, 8-10) and affidavits (exhibits 7, 15). In addition, petitioners were ordered to file an expert report outlining the basis of their theory. Dr. Kozachuk’s first report opined that J.R.S. died as a result of PRES, which can begin soon after vaccination and can last for weeks if it is not fatal. Exhibit 11 at 12. In presenting PRES as a diagnosis, Dr. Kozachuk also argued over the course of approximately seven pages that J.R.S. did not die from SIDS. Id. at 1-7, 12.⁵

The Secretary filed a Rule 4 report shortly after Dr. Kozachuk’s report, and concluded there was insufficient evidence to prove petitioners are entitled to compensation. Resp’t’s Rep. at 10. With the report, the respondent submitted blog posts by Mrs. Swick that called into question the factual basis for some of Dr. Kozachuk’s assumptions. Id. at 7-9. As to Dr. Kozachuk’s opinion, the Secretary noted that Dr. Kozachuk has presented an opinion involving primarily immunology and pathology. Given Dr. Kozachuk’s focus on neurology, the Secretary “question[ed] Dr. Kozachuk’s qualifications to opine in these specialized fields, especially since his opinion appears to contradict the conclusion of the medical examiner.” Id. at 9-10.

The case was then transferred to the undersigned. Order, filed June 5, 2014. Following the transfer, Dr. Kozachuk authored a supplemental expert report in response to the Secretary’s Rule 4 report. This report was filed on August 19, 2014. The supplemental report concluded that additional autopsy studies were required to rule out SIDS as a cause of death and to establish a more certain cause

⁴ The procedural history largely, but not entirely, repeats the procedural history provided in the Ruling Finding Facts.

⁵ The Swicks filed the articles that Dr. Kozachuk cited in his January 6, 2014 report in March 2017.

of death. See exhibit 13 at 2. Dr. Kozachuk also identified a neuroscientist and molecular biologist who could perform additional studies. Id. at 3.

After reviewing the filings in the case, the undersigned determined that there were factual discrepancies concerning the time period from J.R.S.'s vaccination to his death. On October 30, 2014, a fact hearing was held to address factual discrepancies in the record by evaluating the testimony of the affiants. Five people testified. The undersigned considered their testimony as well as the documentary evidence.

Following the hearing, the Swicks suggested findings of fact. Pet'rs' Proposed Findings of Fact, filed Dec. 22, 2014. The Secretary addressed those proposals. Resp't's Resp. to Pet'rs' Proposed Findings of Fact, filed Jan. 20, 2015. On January 7, 2016, the undersigned issued a Ruling Finding Facts.

In the ensuing status conference, the undersigned asked whether the Swicks wanted to obtain additional expert reports, including reports from the doctors whom Dr. Kozachuk identified in his second expert report. The undersigned also asked whether the Swicks wanted to obtain additional material from the autopsy. For both questions, the Swicks indicated that they would consider these ideas. The Swicks also stated that they intended to obtain a revised report from Dr. Kozachuk in which he considered the Findings of Fact just issued.

The Swicks presented a new report from Dr. Kozachuk on April 29, 2016. Exhibit 21. While Dr. Kozachuk noted the Findings of Fact, the essence of his opinion did not change. Dr. Kozachuk stood by his assertion that J.R.S. suffered from PRES, not SIDS. For more information about SIDS, Dr. Kozachuk recommended that Dr. Kinney, a prominent researcher in this field, be consulted. Dr. Kozachuk also maintained that the vaccinations caused J.R.S. to suffer PRES. Id. at 2.

In the next status conference, the Swicks' attorney represented that he intended to attempt to consult with Dr. Kinney. However, the undersigned informed Mr. Moeller that Dr. Kinney appears not interested in participating in litigation. The Secretary's attorney stated that he had learned that the Maryland State Board of Physicians had reprimanded Dr. Kozachuk. Later, on the day of the status conference, the Secretary filed the public order of reprimand as exhibit D. Mr. Moeller stated that he would consult his clients about their preferred course of action.

In a July 11, 2016 status report, the Swicks stated that they were attempting to consult with Dr. Miller, a neuropathologist who has testified on behalf of other petitioners in the Vaccine Program. In the next status conference, the Secretary questioned whether there was a reasonable basis for continued pursuit of this claim.

On August 17, 2016, the Swicks stated in a status report that they were not retaining Dr. Miller. Accordingly, the next step was to allow the Secretary time to respond to Dr. Kozachuk's reports. Order, issued Aug. 24, 2016.

The Secretary's expert is Dr. Kohrman. Dr. Kohrman disputed the diagnosis of PRES based upon the autopsy. Dr. Kohrman also stated: "[J.R.S.]'s autopsy is consistent with asphyxia as noted by the medical examiner but was ruled a SIDS case. He was at risk for SIDS based on his prematurity, and being found in the prone position with his head covered." Exhibit E at 10. Dr. Kohrman also opined: "There is no evidence to link the causation of J.R.S.'s death to his vaccinations on July 25, 2011." Id.

In the status conference to discuss Dr. Kohrman's report, the Swicks were asked whether they wanted to obtain a responsive report from Dr. Kozachuk. The Swicks expressed some interest in conferring with Dr. Kozachuk, and also proposed consulting with Dr. Miller again. See order issued Nov. 10, 2016. Any efforts were not fruitful as the Swicks stated that they would not be presenting any more expert reports. See Pet'rs' Status Rep., filed Jan. 19, 2017.

In a February 9, 2017 status conference, the parties discussed ways of submitting the case for adjudication. The Swicks stated that a hearing was unlikely to generate new evidence, and, therefore, the special master should decide the case based upon experts' reports. The Secretary agreed that the case could be submitted on the papers.

Following this status conference, the Swicks filed the articles that Dr. Kozachuk had cited in his first report. The Secretary filed four additional articles.

Once the evidence was complete, the parties were ordered to submit briefs and, within the briefs, to address the reliability of Dr. Kozachuk's opinion in light of the Secretary's revelation that the Maryland State Board of Physicians had reprimanded him. The Swicks filed a brief on June 12, 2017. The Swicks generally supported their claim. With respect to Dr. Kozachuk's discipline, the Swicks maintained that Dr. Kozachuk had not misrepresented his credentials because "[h]is reports were submitted before any disciplinary action was taken and

before any sanctions were imposed.” Pet’rs’ Br. at 14. The Swicks further argue “the underlying allegations and findings in the disciplinary action do not challenge Dr. Kozachuk’s credibility.” *Id.* Finally, they also argue that Maryland law would preclude a finder of fact from considering the disciplinary report. *Id.* at 15 n.5 (citing Pepsi Bottling Group v. Plummer, 130 A.3d 1047, 1059 (Md. App. 2016)).

The Secretary responded on August 2, 2017. For Dr. Kozachuk, the Secretary argued that although the special master could consider his reports, they should be given less weight. Resp’t’s Br. at 16-19.

Because the time for filing a reply brief has expired, the case is ready for adjudication.

Analysis

The Swicks have failed to present preponderant evidence that the vaccinations caused J.R.S.’s death. Two points underlie this conclusion. Preliminarily, Dr. Kozachuk has offered opinions in fields in which he lacks expertise and Dr. Kozachuk’s background in neurology is not as strong as Dr. Kohrman’s background in neurology. The second and more important reason for denying compensation is that the Swicks have not established that J.R.S. suffered from PRES.

I. Dr. Kozachuk’s Expertise

The question of Dr. Kozachuk’s qualifications was first raised more than three years ago. The Secretary’s report specifically noted the discrepancy between Dr. Kozachuk’s practice area, neurology, and the disciplines on which he was opining.

Multiple cases have endorsed a special master’s consideration of an expert’s credentials. See Depena v. Sec’y of Health & Human Servs., No. 13-675V, 2017 WL 1075101 (Fed. Cl. Spec. Mstr. Feb. 22, 2017), mot. for rev. denied, 133 Fed. Cl. 535, 547-48 (2017), appeal docketed, No. 2017-2527 (Fed. Cir. Sep. 8, 2017); Copenhaver v. Sec’y of Health & Human Servs., No. 13-1002V, 2016 WL 3456436 (Fed. Cl. Spec. Mstr. May 31, 2016), mot. for rev. denied, 129 Fed. Cl. 176 (2016). In this light, a recitation of the expert’s qualifications is appropriate.

Dr. Kozachuk lists his credentials on his curriculum vitae, which was filed on January 6, 2014, as exhibit 12. Dr. Kozachuk attended college in Canada and received a medical degree from the University of Saskatchewan in 1980. He had a

rotating internship at the Hurley Medical Center in Flint, Michigan from 1980 to 1981. Then for approximately two years, he worked as a family physician. From 1983 through 1986, he was a neurology resident at the Cleveland Clinic Foundation and, in the following year, he worked as an internal medicine resident at the same institution. From 1988 through 1990, Dr. Kozachuk held a fellowship at the National Institute on Aging in the laboratory of neuroscience. Next, he worked at Johns Hopkins Medical School as an associate in CNS vasculitis. He also was simultaneously working as a neurologist in private practice. Exhibit 12 at 6.

It appears that in December 1993, Dr. Kozachuk's focus shifted as he began working for various companies investigating pharmaceuticals. This work seems to have lasted through 2001. See id. at 3-4. Since 1996, he has worked as "part-time neurological consultant" to various private practices. Most of this work appears to focus on treating patients with "head trauma and spinal cord injury." Id. at 2. As of the submission of his curriculum vitae, Dr. Kozachuk's "current position" was at the "Neuroscience Team," which provides "clinical diagnoses of patients with both Neurological and Neuropsychological conditions." Id.⁶

As the Secretary points out (Resp't's Br. at 7-8), Dr. Kozachuk's curriculum vitae is also notable for what it does not say. For example, the curriculum vitae does not list a board certification with the American Board of Psychiatry and Neurology. The curriculum vitae does not list any teaching responsibilities at a university or hospital. The curriculum vitae does not list any current hospital privileges with the most recent affiliation occurring in 1994.

These absences lead the Secretary to argue: "Head to head in the field of neurology, respondent's expert, Dr. Kohrman, obviously has far superior credentials to Dr. Kozachuk." Resp't's Br. at 7. Dr. Kohrman received a medical degree from Rush Medical College in Chicago, Illinois, in 1981. He then had an internship and residency in the pediatric Department of the University of Chicago Hospitals and Clinics. He then had a three-year fellowship in pediatric neurology again at the University of Chicago. In 1987, he became board-certified in psychiatry and neurology with a special competency in child neurology. In that same year, he also became board-certified in pediatrics. He has since obtained

⁶ The Secretary presented an excerpt from the website theneuroscienceteam.com that indicates that Dr. Kozachuk's areas of special interest include "Reactions to Vaccines, and the study of Autoimmunology." Exhibit C at 1.

more board certifications in various other disciplines. Exhibit F (curriculum vitae) at 2.

Beginning in 1986 and continuing for more than three decades, Dr. Kehrman has served as faculty member at various medical schools. One of his current responsibilities is to direct the Department of Pediatric Neurology at Akron Children's Hospital. Id. at 1.

Dr. Kehrman's curriculum vitae lists other achievements, such as authoring articles, conducting pharmaceutical research, and acting as a peer reviewer for various journals. These contributions further demonstrate Dr. Kehrman's expertise in the field of neurology.

The field of neurology, however, is not the only relevant field. Dr. Kozachuk has offered opinions about immunology (explaining how a vaccine can cause PRES) and pathology (challenging the finding that J.R.S. died from SIDS). Dr. Kozachuk forthrightly identified other doctors who would be more qualified to issue opinions about these topics. See exhibit 11 at 12 ¶ 15; exhibit 13 at 3. However, the Swicks did not present a report from anyone who concurred with Dr. Kozachuk's opinions in this case.

Like Dr. Kozachuk, Dr. Kehrman appears to lack any specialized training in immunology and pathology. However, any deficit in Dr. Kehrman's background carries less consequence because the petitioners bear the burden of presenting a persuasive case. See Dean v. Sec'y of Health & Human Servs., No. 13-808V, 2017 WL 2926605, at *18 n.12 (Fed. Cl. Spec. Mstr. June 9, 2017).

In short, ample evidence supports a finding that on neurologic topics, Dr. Kehrman has more extensive expertise. The evidence also supports a finding that neither Dr. Kozachuk nor Dr. Kehrman is particularly knowledgeable in immunology and pathology. These findings are important for the analysis that follows in the section below.

But, before leaving the topic of qualifications and credentials, there is one more topic to explore — Maryland's reprimand of Dr. Kozachuk. Procedurally, it is important to note that Dr. Kozachuk's three reports and the Maryland disciplinary order are exhibits in this case. The Secretary did not file a motion to strike Dr. Kozachuk's reports and the Swicks did not file a motion to strike the disciplinary order. Thus, because the reports and the disciplinary order are part of the record, the undersigned must consider them. See 42 U.S.C. § 300aa-13(a).

The directive for a special master to determine compensation based upon “the record as a whole” appears tempered by Vaccine Rule 8(b)(2), stating the special master “must consider all relevant and reliable evidence.” This qualification implicitly seems to recognize that “the record as a whole” may contain some evidence that might not be relevant and some that might not be reliable. Cf. Paterek v. Sec’y of Health & Human Servs., 527 F. App’x 875, 884 (Fed. Cir. 2013) (noting that a special master does not commit legal error in finding some medical history “not relevant”).

Thus, the ensuing question is: is the Maryland disciplinary order relevant? (As an order from an adjudicatory body, the order is *prima facie* reliable.) The Secretary argues that the Maryland disciplinary order is relevant to Dr. Kozachuk’s credibility as an expert witness. Quoting Contreras v. Sec’y of Health & Human Servs., 121 Fed. Cl. 230, 238 (2015) (Contreras VI), vacated on other grounds, 844 F.3d 1363 (Fed. Cir. 2017)), the Secretary contends “an expert who is not credible does not, as a general rule, provide reliable expert testimony.” Resp’t’s Br. at 18.

The Maryland disciplinary order reduces Dr. Kozachuk’s credibility. While the underlying misconduct may not directly affect Dr. Kozachuk’s credibility as defined by the Federal Rule of Evidence 608, the more important issue is that Dr. Kozachuk displayed a lack of candor by not bringing forth the discipline against him. As to this point, the Swicks’ defense of Dr. Kozachuk is based upon an error in regard to the disclosure of his discipline.

The Swicks assert that Dr. Kozachuk’s “reports were submitted before any disciplinary action was taken and before any sanctions were imposed.” Pet’rs’ Br. at 14. The foundation for this argument is an assertion that “Dr. Kozachuk’s most recent report was filed on August 19, 2014.” Id. However, as the Secretary noted, “Petitioners appear to have inadvertently missed Dr. Kozachuk’s report that was internally dated by him on April 29, 2016.” Resp’t’s Br. at 17 n.8. Thus, Dr. Kozachuk had an opportunity in his April 2016 report to disclose the reprimand from his licensing body issued on April 25, 2016. Dr. Kozachuk’s lack of candor makes his case similar to the lack of candor displayed by the Secretary’s expert in Contreras VI, 121 Fed. Cl. at 239 (noting that the expert witness’s lack of candor was one of five reasons that special master should have “at the very least . . . significantly discount[ed]” the opinion from that expert).

While Dr. Kozachuk’s failure to disclose the reprimand diminishes his credibility, ultimately this lapse did not alter the decision in this case. Dr. Kozachuk’s main deficit is his lack of qualifications. Dr. Kozachuk’s lack of

experience is separate from any misgivings about his disciplinary record and his lack of disclosure. In other words, even if Dr. Kozachuk had not engaged in any conduct warranting professional discipline that he should have disclosed, the outcome would have been the same.

II. Dr. Kozachuk's Diagnosis of PRES

The parties dispute whether J.R.S. suffered the injury for which the Swicks seek compensation. On this issue, the Swicks bear the burden of proof. Broekelschen v. Sec'y of Health & Human Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010); Lombardi v. Sec'y of Health & Human Servs., 656 F.3d 1343, 1352 (Fed. Cir. 2011) (“under Broekelschen, identification of a petitioner's injury is a prerequisite to an Althen analysis of causation”). In doing so, the special master is “not ‘diagnosing’ vaccine-related injuries.” Knudsen v. Sec'y of Health & Human Servs., 35 F.3d 543, 549 (Fed. Cir. 1994). Rather, the special master evaluates the evidence presented and determines whether the petitioners have met their burden of establishing that the vaccinee suffers from the disease. See Lombardi, 656 F.3d at 1353–56 (reviewing evidence that the special master considered in determining whether petitioner suffered from a particular disease and finding that the special master's factual findings were not arbitrary or capricious).

In the discussion of whether the Swicks met their burden of establishing, by preponderant evidence, that J.R.S. suffered from PRES, the parties touch on the diagnostic criteria. See Pet'rs' Br. at 24-26 (citing Dr. Kozachuk's reports and four articles); Resp't's Br. at 9 (citing Dr. Kohrman's report and two articles). An abstract from a case report of a 19-year-old pregnant woman with PRES states “Diagnosis of the syndrome can be difficult.” Exhibit 33 (Mehtap Honca et al., Posterior Reversible Encephalopathy Syndrome in an Eclamptic Patient After Cardiac Arrest; Case Report and Literature Review, 42 Turk. J. Anaesth. Reanim. 50-53 (2014)) at 50.⁷

For setting out relevant diagnostic factors, the Endo article is useful because it focuses on pediatric cases of PRES. These authors defined PRES as “a clinical and radiological syndrome, characterized by headache, confusion, seizures, and visual disturbance associated with transient characteristic lesions on neuroimaging, predominantly in the posterior part of the brain.” Exhibit 29 (Ayumi Endo et al., Posterior reversible encephalopathy syndrome in childhood: report of four cases and review of the literature, 28(2) Pediatr Emerg Care 153-57 (2012)) at 153.

⁷ The petitioners' cover page to exhibit 33 does not cite the article accurately.

Whether PRES can occur in children as young as J.R.S. is not entirely clear as another article analyzed pediatric cases of PRES and found that none happened in an infant. Exhibit E, tab 4 (Vivek Gupta et al., Imaging Findings in Pediatric Posterior Reversible Encephalopathy Syndrome (PRES): 5 Years of Experience From a Tertiary Care Center in India, 31(9) J. Child Neuro. 1166-73 (2016)) at 1167.

While Gupta states an “autopsy in posterior reversible encephalopathy syndrome is distinctly rare,” id. at 1171, the record in this case contains one article about the neuropathology of a fatal PRES case. The authors in that article reported that at the autopsy from an eight-year-old girl, “the occipital and cerebellar white matter and focal occipital cortical gray matter showed a spectrum of microvascular changes.” Exhibit 40 (John N. Kheir et al., Neuropathology of a fatal case of posterior reversible encephalopathy syndrome, 13(5) *Pediatr. Dev. Pathol.* 397-403 (2010)) at 397.

To support Dr. Kozachuk’s diagnosis of PRES in J.R.S., the Swicks cite two symptoms and one set of signs as identified by him. For symptoms, the Swicks point to J.R.S.’s fussiness after the July 25, 2011 vaccinations, which may have been due to constipation, and the single episode of vomiting. To the Swicks, J.R.S.’s fussiness “correlated to symptoms of headache, confusion, and decreased alertness in adult.” Pet’rs’ Br. at 25. For signs of PRES, Dr. Kozachuk notes various findings on J.R.S.’s autopsy. See id. at 24, quoting exhibit 11 (Dr. Kozachuk’s first report) at 12.

The Swicks’ presentation is not persuasive. As to symptoms, the fussiness can be set aside because it is more likely than not that J.R.S. was constipated. See exhibit E at 9-10. Eliminating fussiness leaves a single episode of vomiting, involving a relatively large amount of vomit. However, vomiting – even large amounts – is relatively common in children less than four months as any parent knows. This is far too slender a reed to support the PRES diagnosis.

As to signs at autopsy, the Swicks are in a difficult position because they are taking a position contrary to the evaluation of the neuropathologist who examined J.R.S.’s brain. Dr. Kirby’s case summary states “examination of the brain fails to reveal a CNS cause of death. Although somewhat non-specific, the findings would be in keeping with an asphyxial death.” Exhibit 6 at 28. Implicitly, the Swicks are challenging Dr. Kirby’s finding, essentially arguing that she missed signs of PRES. In trying to establish, on a more likely than not basis, the soundness of Dr. Kozachuk’s diagnosis, the Swicks have a challenging task, as autopsy reports “are

contemporaneous records made by a health care professional outside the context of litigation, and should be given the same probative weight as other medical records.” Nordwall v. Sec’y of Health & Human Servs., 83 Fed. Cl. 477, 488 (2008), app. dismissed voluntarily, 331 Fed. App’x 720 (Fed. Cir. 2009). The Swicks’ challenge is even greater because in trying to overturn Dr. Kirby’s neuropathological finding, they are relying upon a doctor who appears to have no specialized training in neuropathology and who even recommended that they seek the assistance of a neuropathologist. Under these circumstances, the Swicks have failed to present persuasive evidence that J.R.S.’s autopsy supports the finding of PRES.⁸

In finding that the Swicks failed to meet their burden of proving that J.R.S. had PRES, the undersigned has considered the parties’ arguments about whether J.R.S.’s death should alternatively be categorized within the group known as Sudden Infant Death Syndrome (SIDS). This general debate encompasses a specific controversy over the significance or non-significance of how J.R.S. was found on the morning of his death — on his stomach. Overall, these disputes were not particularly insightful. While ruling out other possible reasons for J.R.S.’s death could advance the Swicks’ case to some degree, the Swicks do not prevail simply by establishing, on a more likely than not basis, that J.R.S. did not die from asphyxia or SIDS. The Swicks’ burden is to establish that J.R.S. had PRES.⁹ For the reasons explained above, the evidence falls far short.

⁸ A final piece of evidence weighing against the Swicks is that the Secretary’s expert, Dr. Kohrman, stated that J.R.S.’s autopsy “demonstrated no evidence for PRES.” Exhibit E at 9. While Dr. Kohrman’s opinion aligns with Dr. Kirby’s conclusion, Dr. Kohrman’s opinion about neuropathology seems to suffer from a similar impairment as Dr. Kozachuk’s opinion: a relative lack of expertise in neuropathology. In addition, Dr. Kohrman’s analysis is relatively conclusory. Given the numerous technical terms in the autopsy, the Secretary would have been better served if Dr. Kohrman had explained more thoroughly how he reached his opinion. For these reasons, the undersigned has not given Dr. Kohrman’s opinion about neuropathology much weight.

⁹ Dr. Kozachuk’s opinion is that J.R.S. did not die from SIDS. Exhibit 21. Although Dr. Kozachuk recommended additional studies and additional experts, the Swicks did not obtain them. Thus, the Swicks base their claim “upon the facts showing that J.R.S.’s demise was not consistent with the usual associations of SIDS, and instead that the child died as a result of posterior reversible encephalopathy syndrome, or PRES, caused by his vaccinations.” Pet’rs’ Br. at 16.

The Swicks have failed to establish that Dr. Kozachuk presented a persuasive opinion that J.R.S. suffered from PRES. This gap in their proof means that they are not entitled to compensation.

III. Vaccines as a Potential Cause of PRES

Even if the Swicks had established on a more-likely-than-not basis that J.R.S. suffered from PRES, they would still be required to prove with preponderant evidence that the vaccines caused J.R.S.'s PRES. This evaluation would require an assessment of the evidence in light of the Federal Circuit's three-prong test set forth in Althen v. Sec'y of Health & Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). See Broekelschen, 618 F.3d at 1350.

The parties submitted evidence in support of their respective positions. This evidence included the reports from the experts, medical literature, and testimony from the experts. The parties summarized this evidence in their briefs. See Pet'rs' Br. at 19-36; Resp't's Br. at 13-16. The undersigned has considered the evidence and arguments.

Nevertheless, the undersigned declines to determine, strictly as a hypothetical matter, how the causation evidence preponderates. As the Federal Circuit has explained, "[i]n the absence of a showing of the very existence of any specific injury of which the petitioner complains, the question of causation is not reached." Lombardi, 656 F.3d at 1353.

In addition, the inquiry into causation is "frequently more difficult." Hibbard v. Sec'y of Health & Human Servs., 698 F.3d 1355, 1365 (Fed. Cir. 2012). Since any analysis would necessarily be counter-factual in that it would assume that J.R.S. suffered from PRES when preponderant evidence shows that he did not, exploring the more challenging question of whether any relevant vaccine can cause PRES is not necessary to decide the Swicks' case. Therefore, no findings are made regarding their proof under Althen.

Conclusion

The loss of a beloved child so early in his life caused immense grief for the Swicks. They deserve sympathy.

However, special masters are tasked with determining whether petitioners have established that they are entitled to compensation based upon the evidence. Here, the Swicks have not established, on a more likely than not basis, a critical

step in their proof — namely, that J.R.S. suffered from PRES. Without this predicate finding, the Swicks cannot prevail.

The Clerk's Office is instructed to issue a judgment in accord with this decision.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master